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II. AMENDMENTS TO THE CLAIMS

Claim 1. (Currently Amended) A process for the preparation of a an agglomerated solid dosage form, comprising

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- (1) preparing an aqueous slurry of
 - (a) microcrystalline cellulose;
 - (b) a microcrystalline cellulose compressibility augmenting agent which
 - (i) physically restricts the proximity of the interface between adjacent cellulose surfaces;
 - (ii) inhibits interactions between adjacent cellulose surfaces, ~~for~~ example, via the creation of a hydrophobic boundary at cellulose surfaces; or
 - (iii) accomplishes both (i) and (ii) above; ~~and~~
 - (c) an active agent; and
 - (d) an effective amount of a sustained release carrier;

(2) thereafter spray drying the resultant aqueous slurry in a manner which inhibits quasi-hornification, thereby obtaining ~~an agglomerated material~~ particles which ~~is~~ are directly compressible into a solid ~~dosage form~~ sustained release matrix which provides release of the active agent over a time period of about 8 to about 24 hours.

Claim 2. (Currently Amended) ~~A~~ The process of claim 1, further comprising ~~utilizing a spray drying technique to dry the aqueous slurry~~ compressing the agglomerated particles into a tablet.

Claim 3. (Currently Amended) ~~A~~ The process of claim 1, wherein said compressibility augmenting agent is a surfactant having an HLB of at least about 10.

Claim 4. (Currently Amended) ~~A~~ The process of claim 1, wherein said

compressibility augmenting agent is a surfactant having an HLB of at least about 15.

Claim 5. (Currently Amended) ~~A~~ The process of claim 1, wherein said compressibility augmenting agent is a surfactant having an HLB from about 15 to about 40.

Claim 6. (Currently Amended) ~~A~~ The process of claim 5, wherein said compressibility augmenting agent is sodium lauryl sulfate.

Claim 7. (Currently Amended) ~~A~~ The process of claim 5, wherein said compressibility augmenting agent is a polysorbate.

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Claim 8. (Currently Amended) ~~A~~ The process of claim 1, wherein said compressibility augmenting agent further comprises a ~~is a silicon dioxide portion of said agglomerate being derived from a~~ silicon dioxide having an average primary particle size from about 1 nm to about 100 μ m.

Claim 9. (Currently Amended) ~~A~~ The process of claim 8, wherein said silicon dioxide is included in amount from about 0.1% to about 20% by weight, based on the weight of microcrystalline cellulose.

Claim 10. (Currently Amended) ~~A~~ The process of claim 3, wherein said surfactant is included in amount from about 0.1% to about 20% by weight, based on the weight of microcrystalline cellulose.

Claim 11. (Currently Amended) ~~A~~ The process of claim 9, wherein said silicon dioxide is colloidal silicon dioxide.

Claim 12. (Cancelled)

Claim 13. (Currently Amended) ~~A~~ The process of claim ~~12~~ 1, wherein said sustained release carrier is selected from the group consisting of an alkyl cellulose, an acrylic polymer or copolymer, a cellulose ether, a cellulose ester, and mixtures thereof.

Claim 14. (Currently Amended) ~~A~~ The process of claim ~~12~~ 1, wherein said sustained release carrier is selected from natural or a synthetic gums.

Claim 15. (Currently Amended) ~~A~~ The process of claim 1, further comprising adding a film forming agent into the aqueous slurry, and drying the aqueous slurry in such a manner as to obtain agglomerated particles having a film coating.

Claims 16-17. (Cancelled)

Claim 18. (Currently Amended) ~~A~~ The process of claim 15, further comprising compressing the ~~resultant granulate~~ agglomerated particles into tablets.

Claim 19. (Currently Amended) ~~A~~ The process according to claim 1, wherein the aqueous slurry has a solids content of the aqueous slurry is from about 0.5 to about 25%, by weight prior to said spray drying step.

Claim 20. (Currently Amended) ~~A~~ The process according to claim 1, wherein the aqueous slurry has a solids content of the aqueous slurry is from about 15 to about 20%; by weight prior to said spray drying step.

Claims 21-31 (Cancelled)


Claim 32. (New) The product according to claim 1.

Claim 33. (New) The process of claim 1, further comprising admixing a further amount of sustained release carrier with said agglomerated particles and compressing the resulting mixture into tablets.

Claim 34. (New) The process of claim 33, further comprising wet granulating said mixture, and then compressing the resulting mixture into tablets.

Claim 35. (New) The process of claim 33, further comprising adding a further amount of active ingredient to the mixture.

Claim 36. (New) The process of claim 1, further comprising adding a pharmaceutically acceptable filler to the aqueous slurry.

 Claim 37. (New) The process of claim 36, wherein the pharmaceutically acceptable filler is selected from the group consisting of a monosaccharide, a dissacharide, a polyhydric alcohol, inorganic phosphates, sulfates, carbonates and mixtures thereof.

Claim 38. (New) The process of claim 36, wherein the pharmaceutically acceptable filler is selected from the group consisting of sucrose, dextrose, lactose, xylitol, fructose, sorbitol, calcium phosphate, calcium sulfate, calcium carbonate, "off-shelf" microcrystalline cellulose and mixtures thereof.

Claim 39. (New) The process of claim 1, wherein said sustained release carrier includes a release modifying agent that alters the release rate of the active agent from the formulation upon exposure to an aqueous medium.

Claim 40. (New) The process of claim 39, wherein said release modifying agent is selected from the group consisting of calcium sulfate, sodium chloride, potassium sulfate, sodium bicarbonate, lithium chloride, tripotassium phosphate, sodium borate, potassium bromide, potassium fluoride, sodium bicarbonate, calcium chloride, magnesium chloride, sodium citrate, sodium acetate, calcium lactate, magnesium sulfate and sodium fluoride.

Claim 41. (New) The process of claim 1, wherein the slurry includes a plurality of slurries, each of the plurality of slurries containing one of: a) a microcrystalline cellulose; or ii) a microcrystalline cellulose compressibility augmenting agent.

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Claim 42. (New) The process of claim 1, wherein said sustained release carrier is selected from the group consisting of a polylactide, a polyglycolide, a poly(lactide-co-glycolide), a polyanhydride, a polyorthoester, polycaprolactones, polyphosphazenes, polysaccharides, proteinaceous polymers, soluble derivatives of polysaccharides, soluble derivatives of proteinaceous polymers, polypeptides, polyesters and polyorthoesters.

Claim 43. (New) A process for the preparation of a sustained release agglomerated solid dosage form, comprising

- (1) preparing an aqueous slurry of
 - (a) microcrystalline cellulose;
 - (b) a microcrystalline cellulose compressibility augmenting agent comprising:

- (i) silicon dioxide; or
 - (ii) a surfactant selected from the group consisting of sodium lauryl sulfate, docusate salts, alkyl carboxylates, acyl lactylates, alkyl ether carboxylates, N-acyl sarcosinates, polyvalent alkyl carbonates, N-acyl glutamates, fatty acids, polypeptide condensates sulfuric acid esters, polyoxyethylene compounds, lecithin, ethoxylated alcohols, ethoxylated esters, ethoxylated amides, polyoxypropylene compounds, propoxylated alcohols,

ethoxylated/propoxylated block polymers, propoxylated esters, alkanolamides, amine oxides, fatty acid esters of polyhydric alcohols, ethylene glycol esters, diethylene glycol esters, propylene glycol esters, glycerol esters, polyglycerol fatty acid esters, sorbitan esters, sucrose esters, glucose esters, simethicone, acacia, benzalkonium chloride, cholesterol, emulsifying wax, glycerol monostearate, lanolin alcohols, lecithin, poloxamer, polyoxyethylene and castor oil derivatives; or

(iii) a highly polar dye selected from the group consisting of 3,3'-[[1,1'Biphenyl]-4,4'-diylbis-(azo)]bis[4-amino-1-naphthalenesulfonic acid] disodium salt; disodium salt of 6-hydroxy-5-[(2,4-sulfophenyl)azo]-2-naphthalenesulfonic acid; 5-oxo-1-(p-sulfophenyl)-4-[(p-sulfophenyl)azo]-2-pyrazoline-3-carboxylic acid, trisodium salt; disodium salt of 1-p-sulphophenylazo-2-naphthol-6-sulfonic acid; trisodium-2-hydroxy-1-(4-sulfonato-1-naphthylazo) naphthalene-6, 8-disulfonate; disodium 4,4'-(2,4-dihydroxy-5-hydroxymethyl-3, 3-phenylene bisazo)di(naphthalene-1-sulfonate)); tetrasodium 4-acetamido-5-hydroxy-6-[7-sulfonato-4-(4-sulfonatophenylazo)-1-naphthylazo]naphthalene-1,7-disulfonate; disodium 4-hydroxy-3-(4-sulfonato-1-naphthylazo) Naphthalene-1-sulfonate; trisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo) naphthalene-3, 6-disulfonate) and mixtures thereof; or

(iv) a combination of two ^{or} more of (i), (ii) and (iii) above;

(c) an active agent; and

(d) an effective amount of a sustained release carrier; and

(2) thereafter spray drying the resultant aqueous slurry in a manner which inhibits quasi-hornification, thereby obtaining agglomerated particles which are directly compressible into a solid sustained release matrix which provides release of the active agent over a time period of about 8 to about 24 hours.